

### REMARKS

The present response is being submitted in reply to the Final Office action issued on August 7, 2008. Claims 1-24 are pending in this application. By the present response, claims 1-14 and 18 have been amended and claims 25-31 have been added, as discussed below.

Claim 1 has been amended to specify that the adhesive contains at least one component selected from the groups as defined at (a) through (d), with the proviso that the advice further contains (1) at least one film-forming polymer selected from the group of non-pressure-sensitive adhesive polyacrylates (formerly designated as “component (e)”, and/or (2) at least one pressure-sensitive adhesive polymer. The amendment is based on former claim 1, and is further supported by the present specification (paragraphs [00009], [000014], [000021], [000034] and [000035]). It is submitted that claim 1 (and others) have been amended to clarify the term “non-pressure-sensitive polyacrylates” to “non-pressure-sensitive adhesive polyacrylates.”

The proviso “wherein at least two components differ from each other by each being a member of a different class (a) to (e)” has been deleted by the present response since paragraph [00009] of the specification does not require the presence of two components (i.e., “contains a component”), and since the newly added proviso as set forth above requires the presence of a further component which is different from components (a) to (d).

Lastly, the reference to “at least one organic acid” has been deleted from claim 1.

Regarding claims 2 through 9, the claims have been amended to delete the terms “additional” or “further” since the claims originally included said terms to further define

the components of groups (a) through (d) rather than to specify “additional” or “further” ingredients.

Regarding claim 11, the term “pressure-sensitive adhesive polymer” has been added to claim 1. Therefore, claim 11 has been amended accordingly. In addition, the limitation of “40-60%” has been transferred to a new dependent claim since the limitation is only optional (i.e., specification at paragraph [000036]) (new claim 25).

Regarding claim 12, the term “further” has been deleted. In addition, the limitation of “25-96%” has been transferred to a new dependent claim since the limitation is only optional (new claim 26).

Regarding claim 13, the term “organic acid” has been clarified as a “further” component and the preferred organic acids have been transferred to a new dependent claim (new claim 27).

Regarding claim 14, the claim has been amended to depend from claim 13 accordingly.

Regarding claim 18, the claim has been amended in accordance with claim 1. In addition, the step of selecting the solvent has been amended to define the group as consisting of “water, aqueous solvent mixtures, alcohols and esters,” support for which may be found in the specification at paragraph [000033].

Regarding new claim 28, the claim has been added to cover the limitation which was previously set forth in claim 1, namely, “wherein at least two components differ from each other by each being a member of a different class (a) to (d).” It is noted that “(a) to

(e)” has been replaced with “(a) to (d)” since component (e) is already set forth in claim

1. Support may be found in the specification, such as at paragraph [000014].

Regarding new claims 29 – 31, the claims have been added to recite particular combinations of the components set forth in previous claims. In particular, claim 29 relates to an embodiment where one component is selected from group (c) or (d), in combination with a film-forming, non-pressure-sensitive adhesive polyacrylate. Support for these claims may be found in the specification, such as at Example 2 (paragraphs [000047] – [000049]) of the specification, in which Eudragit NE 40 D represents the film-forming, non-pressure sensitive adhesive polyacrylate and Gantrez AN-169 represents component (d). Reference is also made to paragraphs [000018] and [000021] of the specification.

Claim 30 relates to an embodiment wherein one component is selected from group (c) or (d) in combination with a pressure-sensitive adhesive polymer. Support for the claim may be found at the specification, Example 3 (paragraphs [000051] – [000053], as well as paragraphs [000034] and [000035]).

Regarding claim 31, the claim relates to an embodiment where one component is selected from cellulose derivatives (b) in combination with a pressure-sensitive adhesive polymer selected from polyacrylates, polyisobutylenes, polyisoprenes or silicone adhesives. The claim was derived from combining former claims 1 and 11, support for which may be found in the specification at paragraphs [00009], [000015], [000034] and [000035].

The specification has been amended to correct the spelling of the term  
“melanotropin.”

No new matter has been added. Reconsideration is respectfully requested in light  
of the amendments being made hereby and of the following remarks.

**Rejection of claims 1-3, 6, 9-10 and 13-21 under 35 U.S.C. 102(e)**

Claims 1-3, 6, 9-10 and 13-21 have been rejected under 35 U.S.C. 102(e) as being  
anticipated by U.S. Patent No. 6,375,963 (Repka, et al.). The Examiner essentially  
concludes that Repka, et al. disclose every limitation recited in the aforementioned  
claims. In particular, the Examiner states that Repka, et al. teach a bioadhesive hot-melt  
extruded film for topical and mucosal adhesive applications and a drug delivery and  
process for preparation thereof. In particular, the Examiner states that Repka, et al. teach  
a hot-melt extruded film for the transdermal or mucosal administration of active  
substances whose adhesive force develops after humidification. The Examiner further  
states that Repka, et al. teach a film for the treatment of wounds which contains, *inter  
alia*, hydropropyl cellulose, polyvinyl pyrrolidone, carbomer and polycarbophil, which  
film can be connected to an overlaying adhesive patch. Repka, et al. also disclose in  
Example 7, a vitamin E adhesive patch that guards against wrinkles and senile lentigo,  
and contains, *inter alia*, Gantrez MS-955, polycarbophil and hydroxypropyl cellulose, as  
well as that the bioadhesive film also contains organic acids such as tartaric acid and  
acrylic polymers.

The Applicants respectfully disagree with the Examiner's conclusion and submit  
that the present invention as defined in the present claims is patentably distinct from the

invention disclosed in the prior art Repka, et al. reference. In particular, the reference fails to disclose any adhesive compositions which contain a film-forming polyacrylate or a pressure-sensitive adhesive polymer in combination with one or more components as defined in groups (a) to (d) of the present claims. In this regard, the Examiner has referred to claim 30 of Repka, et al. for disclosing "acrylic polymers." However, this term does not disclose "film-forming, non-pressure-sensitive adhesive polyacrylates" or "pressure-sensitive adhesive polymers," as recited in present claim 1. In general, the polymers to be used in the invention of Repka, et al. are selected to be suitable for hot-melt extrusion processing (col. 5, lines 4-13). This also applies with respect to the "acrylic polymers" mentioned in claim 30 of Repka, et al. In column 4, lines 11-15, the "acrylic polymers" are listed as bioadhesive polymers which clearly implies to one skilled in the art that these polymers are capable of promoting adhesion to biological surfaces, such as skin or mucosal surfaces. However, "bioadhesive" is clearly not the equivalent of "pressure-sensitive adhesive" and polymers having bioadhesive properties do not necessarily also have pressure-sensitive adhesive properties in accordance with the presently claimed invention.

Regarding claim 18, Repka, et al. fail to teach a step of including a solvent since the teaching of Repka, et al. is limited to hot-melt extrusion processing (see, for example, Abstract and claim 24).

In conclusion, it is submitted that the Repka, et al. fail to teach each and every limitation of the present claims and therefore the reference does not anticipate the presently claimed invention. Withdrawal of the present rejection is respectfully

requested.

**Rejection of claims 4-5, 7-8, 11-12, 22, 24 and 33 under 35 U.S.C. 103(a)**

Claims 4-5, 7-8, 11-12, 22 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Repka, et al. in view of U.S. Patent No. 6,682,721 (Kim, et al.). The Examiner states that Repka, et al. fail to teach the ingredients as set forth in claims 4, 5, 7, 8, 11 and 12. In turn, the Examiner refers to Kim, et al. and states that the reference discloses patches for teeth whitening which substantially discloses the presently claimed invention. The Examiner further states that Kim, et al. teach a number of polymers can be used alone or in combination to produce moisture activated adhesives, including PVM/MA copolymers and polyvinyl alcohols. The Examiner states that the examples show that combinations of, for example, Gantrez S-97 with polyvinyl pyrrolidone (Example 6) or polyvinyl alcohol with polyvinyl pyrrolidone (Example 1) have the desired adhesive force on a moist substrate. The Examiner concludes that absent a critical teaching and/or a showing of unexpected results, it would have been obvious to one having ordinary skill in the art to combine the polymers specified in Repka, et al. through routine experimentation with the polymers specified in Kim, et al. for the production of an adhesive layer that has an improved adhesive force on moist surfaces.

Claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over Repka, et al. in view of U.S. Patent No. 3,322,703 (Lindemann). The Examiner states that Repka, et al. fail to teach carboxylic acid in the adhesive composition. The Examiner refers to Lindemann and states that the reference teaches that it is known to use an organic acid such as carboxylic acid in the preparation of remoistenable adhesives in order to

accomplish the esterification process. The Examiner concludes that it would have been obvious to one having ordinary skill in the art to substitute the acid used for esterification in Repka, et al. for the carboxylic acid as disclosed by Lindemann depending upon which polymeric material is used.

The Applicants respectfully disagree with the Examiner's position and submit that to establish a *prima facie* case of obviousness, three basic criteria must be met, as set forth in M.P.E.P. § 2142. First, there must be some suggestion or motivation to modify the reference or to combine the reference teachings. Second, there must be a reasonable expectation of success. Third, the prior art reference (or references when combined) must teach or suggest all the claim limitations.

It is respectfully submitted that the Kim, et al. and Lindemann references fail to make up for the numerous deficiencies of Repka, et al., as discussed above. In particular, Kim, et al. fail to teach combining film-forming polyacrylates or pressure-sensitive adhesive polymers in an adhesive composition containing at least one of components (a) through (d), as recited in present claim 1. According to Kim, et al., film-forming polymers may be included in the backing layer (col. 8, lines 51-54) which, however, is clearly different from the adhesive layer.

With respect to claims 4, 5, 7, 8, 11 and 12, the Examiner states that Kim, et al. teach a number of other polymers (such as PVM/MA copolymers, polyvinyl alcohols, polyvinyl, pyrrolidone) that may be used to produce moisture-activated adhesives. However, with reference to present claim 1 as amended, Kim, et al. fail to teach or suggest combining a moisture-sensitive adhesive composition (components (a) through

(d) in present claim 1) with at least one film-forming polymer selected from the group of non-pressure-sensitive adhesive polyacrylates and/or at least one pressure-sensitive adhesive polymer. Therefore, it is submitted that the cited secondary references fail to make up for the numerous deficiencies Repka, et al. and therefore the present claims are not rendered obvious.

It is therefore respectfully submitted that the present invention defined in the present claims is patentably distinguishable over the prior art teachings under 35 U.S.C. 103(a). Based on the aforementioned differences between the presently claimed invention and the prior art, each and every element of the present invention recited in the present claims are not set forth in the combined teachings of the prior art. Moreover, one skilled in the art would not be motivated to modify the prior art to arrive at the presently claimed invention. Even if one were to do so, there would be no expectation of success. Therefore, the Applicant respectfully requests that this rejection be withdrawn.

### **Conclusion**

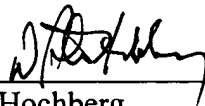
For the foregoing reasons, it is believed that the present application, as amended, is in condition for allowance, and such action is earnestly solicited. Based on the foregoing arguments and the deficiencies of the prior art reference, the Applicants strongly urge that the obviousness-type rejection be withdrawn. The Examiner is invited to call the undersigned if there are any remaining issues to be discussed which could expedite the prosecution of the present application.



Respectfully submitted,

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